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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,350	10/31/2003	Kuldeep Singh Neote	PFA-008.01	9666

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,350	NEOTE ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method for identifying a candidate therapeutic agent for a CD8+ T cell priming disorder comprising in evaluating whether a candidate compound interacts or changes a gene of figure 1 or 2, classified in class 435, subclass 4. For reasons explained below, election of this group requires the further election of a single gene selected from figure 1 or figure 2. Election of this group also requires the further election of a compound recited in claim 2. Note these are not species elections. Election of this group requires a further species election between in vitro assays and in vivo assays.

II. Claims 8-14, drawn to a method for identifying a candidate therapeutic agent for a CD8+T cell priming disorder comprising in evaluating whether a candidate compound interacts or changes a gene product of figure 1 or 2, classified in class 435, subclass 6. For reasons explained below, election of this group requires the further election of a single gene selected from figure 1 or figure 2. Election of this group also requires the further election of a compound recited in claim 9. Note these are not species elections. Election of this group requires a further species election between in vitro assays and in vivo assays.

III. Claims 15 and 16, drawn to a method for identifying a candidate therapeutic agent for a CD8+T cell priming disorder comprising in evaluating whether a candidate compound interacts or changes a protein encoded by a gene of figure 1 or 2,

classified in class 435, subclass 7.1. For reasons explained below, election of this group requires the further election of a single gene selected from figure 1 or figure 2. Note this is not a species election.

IV. Claims 17-19, drawn to a method of evaluating the efficacy of a candidate therapeutic for a CD8+ T cell priming disorder comprising treating a subject having said disorder and correlating it with the expression level of at least one gene from figure 1, classified in class 514, subclass 1.

V. Claims 20-28, drawn to a solid surface which are linked to a plurality of detection agents that are capable of detecting genes or the polypeptides encoded thereby that are differentially expressed during CD 8+ T cell priming, whereby the genes are listed in figure 1 or 2, classified in 536, subclass 24.3. Election of this group requires the further election of detecting either genes or polypeptides. Election of this group requires the further election of a single gene from either of figure 1 or figure 2. Note these are not species elections.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions do not overlap in scope, since Groups I-III each comprise the use of different structures, such as genes (i.e. DNA), gene products (i.e. RNA) or protein. Group IV has different steps related to treating a subject having a

disorder, which are not shared by any other group, and therefore does not overlap in scope with any other group. Because these groups have either unique structures or unique steps not shared by any other group, the inventions are also therefore not obvious variants, and have at least a materially different design. Since is it is a burden to search and examine these multiple inventions in the single application due to the fact that the searches are divergent and non-coextensive, restriction is proper therefore.

Invention V is related to those of I-IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the array of Group V can be used to measure changes in the expression of any gene during any dynamic cellular process, and not just for determining changes in gene expression that occurr only during CD8+ T cell priming. Since is it is a burden to search and examine these multiple inventions in the single application due to the fact that the searches are divergent and non-coextensive, restriction is proper therefore.

The genes listed in figures 1 and 2, as well as the classes of compounds listed in claims 2 and 9 are directed to distinct products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each product has its own structure that does not render any other structure obvious and does not overlap in scope with any other. Since each thus has at least a unique

materially different design, and since it is a burden to search for such multiple structures since the searches are divergent and non-coextensive, restriction is proper therefore.

This application contains claims directed to the following patentably distinct species: in vitro and in vivo assays. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 or 8 (depending on the elected Group) is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER